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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,258	07/31/2003	Claude F. Meares	023070-130920US	1595

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MORGAN, LEWIS & BOCKIUS LLP (SF)
2 PALO ALTO SQUARE
PALO ALTO, CA 94306

EXAMINER

FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/631,258

Applicant(s)

MEARES ET AL.

Examiner

Brandon J. Fetterolf, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-38 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Meares et al.

DETAILED ACTION

Election/Restrictions

The Election filed on May 10, 2005 in response to the Restriction Requirement of February 10, 2005 has been entered. Applicants have elected Group V, claim 39, as specifically drawn to a Claim 39, as specifically drawn to a polypeptide. Applicants have further elected SEQ ID NO: 13 as the ONE polypeptide for consideration.

Applicant's election with traverse of Group V, claim 39 is acknowledged. The traversal is on the ground(s) that the claims of Group V have been amended to be either directly or indirectly dependent upon claim 1, and recited a method of treating cancer by administering an antibody having the recited feature to a subject. Therefore, each of the pending claims emerges from a common idea or concept and accordingly, Applicants assert that the claims should be properly rejoined and examined as a whole. These arguments have been carefully considered but are not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct.

First, Applicants' assertion that the claims of Group V recite a method of treating cancer by administering an antibody is moot. In the instant case, it appears that Claim 39 is drawn to a product, i.e. a polypeptide of SEQ ID NO: 13, and not to a method of treating cancer. Moreover, it does not appear that claim 39 has been amended to directly or indirectly depend from claim 1, i.e. a mutant antibody. Therefore, the inventions of the various groups are distinct for the reasons set forth in the restriction requirement February 10, 2005.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-42 are pending.

Claims 1-38 and 40-42 have been withdrawn from consideration as being drawn to a non-elected invention.

Claim 39 is currently under consideration.

Information Disclosure Statement

The information disclosure statement filed 10/31/2003 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. The following reference appears to have been submitted to the Office for consideration but has not been cited on the IDS, WO 00/74729.

Specification

The specification/drawings (filed on 7/31/2003) are objected for improper disclosure of amino acid sequences and nucleotide sequences without a respective sequence identifier, i.e. a SEQ ID NOs; see for example Figures 1-11. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d).

Claim Objections

Claim 39 is objected to because of the following informalities: Claim 39 recites non-elected subject matter such as polypeptides comprising an amino acid sequence selected from SEQ ID NOs: 10, 11, 12, 14, 22, 23, 27, 28, 35, 36, 37, 38, 39 and 40. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 39, as written, does not sufficiently distinguish over polypeptides, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught by page 70, paragraph 280 of the specification. See MPEP 2105.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8 and 10-42 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-41 of copending Application No. 10/350,555. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

In the instant case, there does not appear to be any difference between the claims of copending Application No. 10/350,555 and the claims present in the instant application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 10-15 of copending Application No. 10/625,047.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because a species anticipates a genus. In the instant case, the method of treating comprising administering a genus of antibodies comprising an antigen recognition domain that recognizes a macrocyclic metal chelate claimed in the conflicting application, appears to fall within the same scope as the method of treating comprising administering a mutant antibody comprising an antigen recognition domain that recognizes a macrocyclic metal chelate claimed in the application being examined and, therefore, a patent to a method of treating a subject comprising administering a genus of antibodies comprising an antigen recognition domain that recognizes a macrocyclic metal chelate, would necessarily extend the rights of a method of treating a subject comprising administering a mutant antibody comprising an antigen recognition domain that recognizes a macrocyclic metal chelate should the application being examined issue as a patent before the conflicting application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 10-13, 20-23 and 25-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 17-21, 24-25 and 42 of copending Application No. 09/671,953.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because a species anticipates a genus. In the instant case, the genus of mutant antibodies comprising a complementarity determining regions that recognize a metal chelate claimed in the conflicting application appears to fall within the same scope as the genus of mutant antibodies comprising an antigen recognition domain that recognizes a macrocyclic metal chelate claimed in the application being examined and, therefore, a patent to a mutant antibody comprising an antigen recognition domain that recognizes a metal chelate would necessarily, extend the rights of a mutant antibody comprising an antigen recognition domain that recognizes a macrocyclic metal chelate should the application being examined issue as a patent before the conflicting application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Therefore, NO claim is allowed.

Note: An isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 13 appears to be free of the prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
6/22/05